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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/473,713	12/29/99	THATCHER	G 1995-033-12U

EXAMINER	
DELACROIX MUIRHEI, C	
ART UNIT	**PAPER NUMBER**
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STEPHEN J SCRIBNER
PARTEQ INNOVATIONS
QUEENS UNIVERSITY
KINGSTON ON K7L 3N6
CANADA

AIR MAIL

DATE MAILED: 07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/473,713	Applicant(s) THATCHER et al.
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 8, 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *11-20, 22, 24, 26, and 28* is/are pending in the application.

4a) Of the above, claim(s) *12, 15, and 26* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *11, 13, 14, 16-20, 22, 24, and 28* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *5,6*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

The following is responsive to Applicant's election received June 8, 2001.

1. Applicant's election without traverse of Group II in Paper No. 9 is acknowledged. Applicant's further election of the species represented by compound IVk is also acknowledged.

A search was done for the elected species but no prior art was found. The search was expanded to the species represented by the compound Va (page 33).

Claims 12, 15 and 26 are withdrawn from consideration. The elected specie appears to read on claims 11, 13, 14, 16-20, 22, 24 and 28.

Information Disclosure Statement

Applicant's Information Disclosure Statements received April 28, 2000 and May 9, 2000 have been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Claim Objections

2. Claim 13 is objected to because of the following informalities: in claim 13, page 78, lines 8-9, the () should be deleted Furthermore, at line 7, before "amino" --an-- should be added, and after "amino" -- group comprising-- should be added. Both occurrences of the term "including" at line 8 should be deleted. This is so the claims will be consistent with US patent practice. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claims 13-14, 16-20 and 22, 24, 26, 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly

set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" or the Examiner submits **"preferably"** and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 13 recites the broad recitation "substituted or unsubstituted aliphatic group" (line 22 and line 3, page 78), and the claim also recites "preferably" followed by a narrower statement of the range/limitation, i.e. "branched or straight chain aliphatic moiety".

The term "preferably" should be deleted from the claims.

5. Regarding claim 13, line 5, page 78, the phrase "for example(e.g.)" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> > (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 11, 13, 14-20, 22, 24 and 28 are rejected under 35 U.S.C. 102(a) as being anticipated by Thatcher et al., 5,807,847.

Thatcher et al. teach a method of effecting "tissue relaxation" in a patient in need thereof, the method comprising administering an effective amount of a pharmaceutical composition containing an aliphatic

nitrate ester such as the compound of Formula (1) at col. 4. This compound corresponds to Applicant's species represented by Formula Va at page 33. Please see col. 2, lines 64-67; col. 3, lines 1-29.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 11, 13, 14-20, 22, 24, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thatcher et al., 5,883,122.

Thatcher et al. disclose methods for treating patients suffering from trauma to the head, dementias, myocardial infarction, epilepsy, or alcohol withdrawal, the methods comprising administering an effective amount of a nitrate ester compound such as the compound represented by Formula (1) at col. 7 along with a pharmaceutically acceptable carrier. Please see col. 11, lines 19-20; col. 12, lines 18-52.

Thatcher et al. do not specifically disclose that the compound sedates or mitigates anxiety; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made because pain and anxiety are often associated with myocardial infarctions, dementia, trauma, or withdrawal symptoms. Therefore, it would obviously follow from the prior art's method, which administers a compound that is identical to the one claimed by Applicant, that any anxiety or pain accompanying the condition would be effectively treated or alleviated.

Conclusion

Claims 11, 13, 14-20, 22, 24 and 28 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM

June 28, 2001

Cybille Delacroix-Muirheid
Patent Examiner Group 1600